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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/474,478      | 12/29/1999  | B. JACK LONGLEY      | 58434-A/JPW/        | 2296             |

7590 07/16/2002  
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EXAMINER

GITOMER, RALPH J

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1627

DATE MAILED: 07/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/474,478

Applicant(s)

Longley

Examiner

Ralph Gitomer

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 20, 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12-19, 23-26, 28-31, 33, 34, and 39-49 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-19, 23-26, 28-31, 33, 34, and 39-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

The CPA request received 5/20/02 has been entered and claims 1-9, 12-19, 23-26, 28-31, 33, 34, 39-49 are currently pending in this application.

5 A priority date of 5/6/99 is granted. Applicant is again requested to inform the examiner how this present CIP application differs from the parent application which is not currently available to the examiner. A copy of the claims of 09/306,143 and how the two specifications differ is requested.

10 In response to the requirement for Election of Species of 7/13/00, Applicant has elected:

A method of preventing or treating cutaneous inflammation by inhibiting KIT protein.

15 A reading of the specification as originally filed reveals inhibiting the KIT protein may have been performed by administering ACK2 monoclonal antibodies. No other method to do so is seen and there may be a question of enablement as the elected invention is directed to preventing or treating.

20 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

25 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 12-19, 23-26, 28-31, 33, 34, 39-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Columbo in view of Mohammadi.

What has been searched and considered here is:

5 A method of preventing or treating cutaneous inflammation by inhibiting a KIT protein.

Columbo (J of Immunology) entitled ~~✕~~The Human Recombinant c-kit Receptor Ligand, rhSCF, Induces Mediator Release From Human  
10 Cutaneous Mast Cells and Enhances IgE Dependent Mediator Release From Both Skin Mast Cells and Peripheral Blood Basophils~~✕~~ teaches in the abstract, a ligand for the c-kit proto oncogene receptor, a member of the tyrosine kinase receptor class, and the effects of c-kit receptor ligand stem cell factor on the release of  
15 inflammatory mediators from human skin mast cells. There were effects on mast cells related to human allergic reactions and SCF may modulate mast cells function under physiologic conditions. On page 604 column 1, antibodies which recognize human c-kit receptor is shown. On page 606 column 2 last paragraph bridging  
20 to 607, the antibodies against c-kit receptor and their effects were discussed.

The claims differ from Columbo in that they are directed to preventing or treating specifically where Columbo is measuring  
25 effects.

Mohammadi (Science) entitled Structures of the Tyrosine Kinase Domain of Fibroblast Growth Factor Receptor in Complex with Inhibitors teaches on page 955, protein tyrosine kinases are critical components of signaling pathways and selecting inhibitors have considerable therapeutic value.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to specifically treat with inhibitors as taught by Mohammadi in the method of Columbo because the inflammatory effects related to c-kit and that such effects are modifiable are taught by Columbo. Mohammadi is directed to inhibiting the same pathways as Columbo for therapeutic reasons. The connection between c-kit and cutaneous inflammation is clearly shown by Columbo. To select a known antibody such as ACK2 in view of Columbo who selects other antibodies would have been obvious because it would have the expected result.

Applicant's arguments filed 3/28/02 have been fully considered but they are not persuasive.

Applicant argues that Columbo describes in vitro experiments in contrast to the claimed method which is directed to in vivo methods. One cannot base in vivo methods on in vitro experiments because they are not completely predictable. Mohammadi does not teach a mast cell system.

It is the examiner's position that the in vitro experiments of Columbo are highly suggestive of inhibiting the stem cell factor signaling pathway to treat cutaneous inflammation which is why the study was performed. One routinely bases in vivo methods upon in vitro experiments which is why in vitro experiments are performed and one would have a high expectation of success in doing so. Mohammadi was cited to teach the therapeutic value of inhibiting the tyrosine kinases.

Claims 1-9, 12-19, 23-26, 28-31, 33, 34, 39-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The elected invention is directed to preventing or treating cutaneous inflammation. Applicant is invited to specifically point out where in the specification a method of preventing or treating cutaneous inflammation is found.

Since an election of species was made, no other issues under 35 USC 112 will be considered here regarding the presently pending claims.

Applicant's arguments filed 3/28/02 have been fully considered but they are not persuasive.

Applicant argues that the specification teaches administering compounds to prevent or treat cutaneous inflammation.

It is the examiner's position that the specification does not enable one of skill in this art to make and use the invention as elected. For example, no specific compounds are shown to be administered to any person for a specific function and the results of the administration determined. The present specification on page 9 directed to Fig. 8 does not appear to be directed to cutaneous inflammation and does not enable treating humans.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the

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statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier  
5 communications from the examiner should be directed to Ralph  
Gitomer whose telephone number is (703) 308-0732. The examiner  
can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm.  
The examiner can also be reached on alternate Mondays. If  
attempts to reach the examiner by telephone are unsuccessful, the  
10 examiner's supervisor, Joseph McKane can be reached on (703) 308-  
4537. The fax phone number for this Art Unit is (703) 308-4556.  
Any inquiry of a general nature or relating to the status of this  
application should be directed to the Group receptionist whose  
telephone number is (703) 308-1234. For 24 hour access to patent  
15 application information 7 days per week, or for filing  
applications electronically, please visit our website at  
[www.uspto.gov](http://www.uspto.gov) and click on the button Patent Electronic Business  
Center for more information.

*Ralph Gitomer*

Ralph Gitomer  
Primary Examiner  
Group 1627